Michigan Department of Community Health: Michigan BioTrust for Health

Joint Community Values Advisory Board (CVAB), Scientific Advisory Board (SAB) and MI Neonatal Biobank (MNB)Board of Directors (BOD) Meeting: Minutes

Date: December 6, 2010

Location: Michigan Neonatal Biobank, WSU Techtown, 440 Burroughs, Detroit MI 48202

Members Present

CVAB: *Vicki Rakowski (Chair), Rosalyn Beene Harris, JohnRoy Castillo, Denise Chrysler, Kara Hamilton, Tedra Jackson, Dan Korobkin, Neil MacVicar, Stephen Rapundalo (SAB representative also), Amy Zaagman, Carrie Langbo (MDCH Facilitator)*

SAB: *Kevin Cavanagh, Glenn Copeland, Violanda Grigorescu, Sue Land, Dorene Markel, Paul Montgomery, Doug Ruden, Gary Smith, Beverly Yashar*

BOD: *Ed Goldman (President), Nancy Christ, Gloria Heppner, Denise Holmes, Frances Pouch Downes (SAB Representative also), James Resau*

Guests: *Janice Bach, Jean Chabut, Randall Charlton, Katie Daenzer*

Agenda Item	Comments / Conclusion / Recommendations	Action / Follow-Up *Responsible Member(s)*
Welcome & Introductions	• Opening remarks made by Randall Charlton. • Further opening remarks made by Ed Goldman, President of MNB BOD. Mr. Goldman's involvement with dried blood spots (DBS) began in 1998 while chairing a committee on genetic privacy and progress which recommended the use of DBS in health research. Subsequently Michigan's (MI) public health code was amended and the BioTrust was created with CVAB & SAB as components. • Introductions of board members made.	
House-keeping	• Specific time allotted during the meeting for guest comments.	
MDCH Progress Report *Carrie Langbo*	• SAB acknowledged. Established in order to provide a pool of individuals to draw from when convening review panels to ensure scientific merit of the proposal. SAB integral for maintaining scientific integrity of BioTrust. • October 1, 2010: 89 birthing hospitals asked to implement BioTrust parental consent process. Best practices identified during early implementation phase with 11 hospitals in spring 2010. All 89 hospitals contacted individually to arrange for staff training via on-line modules, a webcast or in-services by MDCH staff. >500 nursing CEs issued. ~10 hospitals required independent IRB reviews/approvals. • Preliminary data: All birthing hospitals have initiated consent process. ~90% of consent forms are being returned. Of those, 65% are signed granting consent for use of DBS, 13% declined (denoted by checkbox) and 22% are blank indicating either a "decline" or a circumstance in which the consent process has not taken place. Quarterly reports will be sent to hospitals and will allow for monitoring disparities across the state. • Primary focus of community engagement and education has been on implementation of the consent process and training the workforce, but in addition 12 community events were held in 2010 reaching over 1000 people; DCH staff attended 18 other venues (WIC clinics, public health department visits, grand rounds, and various lectures to professional and advocacy organizations), educating 500 people.	• Copy of BioTrust consent form attached with minutes. DCH now instructs hospitals to mark "Parent Declined" checkbox vs. leaving the form blank when a parent declines participation in the BioTrust to allow for more accurate accounting of the actual consent process. However, all blank forms will continue to be considered as a "decline". • NBS program to include consent form return rate on quarterly reports to hospitals and identify need for additional outreach education regarding parental consent process. • Focus for 2011 will be

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		continued community education/ awareness and development of consent process evaluation.
NBSTRN Virtual Repository *Amy Hoffman, Barry Thompson, and Michael Watson*	• Ed Goldman declared a conflict of interest as NBSTRN committee member, but happy to serve as MI liaison. • Michael Watson provided NBSTRN background before reviewing slides aimed at addressing questions submitted by CVAB. NBSTRN is sponsored by NIH/NICHD and is part of a broader effort to increase avenues for research related to NBS. NBSTRN is the national coordinating center developing resources and infrastructure . A national approach is necessary to collect sufficient data to research very rare NBS disorders. Goal is to acquire information on >5 million DBS to ensure informative data. • Presentation of NBSTRN Virtual Repository ensued. Please refer to attached slides for summary. Additional elements addressed: - Virtual specimen defined as one that is physically maintained/ controlled by individual states. It is linked to NBSTRN software and only certain data elements, agreed upon by each state, are seen. Each state has administrative access/data control. - If a patient requests DBS destruction, the state will destroy the specimen and information about it will be removed from the NBSTRN repository. If a researcher already has the specimen, they will be notified but data may already have been generated using the de-identified specimen. - Four workgroups involved in development of NBSTRN: (1) NBS programs and labs; (2) Clinical centers group; (3) Bioethics and legal issues group; (4) IT and infrastructure development - Some states have declined participation primarily citing legislative restrictions on using DBS in research but many considering participation still at a later date. • Comments: (1) after this explanation board members very supportive of idea; (2) concern expressed regarding out-of-state researchers pulling resources from MI researchers and more quickly depleting the supply; (3) national databanks are occurring more frequently and have already demonstrated utility in studying rare diseases; (4) like the idea that control still stays in states' hands- this is simply a "teaser" about what is available; (5) priority should not just be MI citizens but research as a whole that will benefit all populations; (6) one value is the collaboration- true power of studies will come from pulling samples from many	• CVAB submitted questions to NBSTRN. Please see attached document. • NBSTRN PowerPoint Presentation is attached. • Further discussion is needed regarding Michigan's participation with the NBSTRN Virtual Repository. • Dr. Frances Downes, MDCH Director of Laboratories, will explore further the specific information NBSTRN would like to obtain from Michigan and this will be shared with the boards for further comments and recommendations. • Future Agenda Item: NBSTRN.

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	states.. impossible to do many genetics studies unless collaboration occurs; and (7) potential for core laboratory in MI	
CVAB Progress Report *Vicki Rakowski*	• The importance of representing the public was emphasized; presentation reviewed the board's progress since it convened. Please review attached PowerPoint for summary.	• PowerPoint Presentation is attached.
MNB Progress Report *Ed Goldman*	• SAB members given an opportunity for comments/updates. No additional comments were made at this time. • BOD is focusing on 3 issues: (1) financial stability; (2) educating the public and researchers; and (3) looking at proper DBS storage and research use. Officers were elected during their first meeting with E. Goldman elected as president. - (1) Donations have been made from research institutions, and VAI provided software to allow proper DBS storage. MSU, WSU, and UofM have provided sweat equity and financial support. When looking at financial stability, it doesn't mean the highest bidder will receive DBS. - (2) Education is high priority; open to travel and speaking to any group. Editorial board interviews have resulted in complimentary stories to date. Want 100% of the consent forms returned, with a good rate of consent but also some people opting out ensuring people are being given opportunity to make a choice. Education is the key especially regarding DBS collected prior to consent. Need to determine how best to educate and inform people about the use of DBS in research, thus want to continue joint meetings with CVAB and SAB in order to build internal trust as well. Nationally has been received very well. • Biobank has informally been approached by other states regarding the potential storage of DBS on their behalf. • Requests for destruction of dried blood spots discussed; relatively few requests have been received. Providing accurate information and allowing transparency is crucial; with further awareness of BioTrust policies there may be an increase in the number of people wishing to opt out of research use for their historical samples.	• Continued joint CVAB, SAB and MNB BOD meetings are important and requested. Carrie will arrange another joint meeting of the boards in 6 months. A date will be forthcoming. • Future Agenda Items: (1) best strategies for educating the public and increasing awareness; (2) Financial viability; (3) update on % consenting and numbers opting-out of use of historical specimens. • SAB requested further thought and discussion about storing and using DBS collected from children ages 1-2 for lead screening. These specimens are currently not stored. Formal discussion about storage and use can be pursued at a later date if interest persists.
DBS Research Report *Nancy Christ*	• 7 orders processed as noted in the research table maintained on the BioTrust website • Several formal inquires have been made with PIs currently completing grant applications prior to submitting a protocol for use of DBS.	•BioTrust Research Table: www.michigan.gov/biotrust. Abstracts and/or summaries being added.
Industry Use of DBS and Royalty Issues *Ed Goldman*	• Biobank must generate funds for recovery of costs. Industry use of DBS follows the same guidelines and review protocols as academia and non-profit agencies. • Fee structure adjusted as more information is collected from other states/registries regarding appropriate fees to charge. Current	•The Department and MNB BOD will continue to assess other states' fee schedules to ensure appropriate fees set for

	plan is to charge academia a fee to simply recover costs while industry might be charged more than just cost recovery. This allows up-front payment from industry which is much easier vs. partnering with a company to share the risks and potential rewards. If one shares the risk, then one must fund part of the research and the BioTrust currently does not have funds for this. Attempting to collect royalties at a later point is also a very difficult process. • Primary goal is to use this resource for sound research, but money can't be lost in the process or it will not be sustainable. The approach currently is to provide DBS for a stated upfront cost under a contract (Material Transfer Agreement) that outlines stipulations of use including provision of study results.	use of Michigan's DBS. • Future agenda item: further discussion about potential core labs in Michigan, collaboration and financial stability.
Public Comments/ Additional Discussion	• Opportunity for guest comments; none made. • The SAB has not met as a separate Board because its role is to provide expertise the Department can utilize in convening Scientific Review Panels for specific BioTrust proposals. These reviews take place independently. After approval, the study information is posted on the BioTrust website. Review panel members also receive a summary of the review. • SAB members made a request to convene as a separate board to discuss issues regarding best approaches to reviewing individual proposals and global scientific issues.	• Carrie will re-send copies of the SAB Review Panel summaries to the individual panelists that took part in the review. • Carrie will facilitate scheduling one SAB meeting within 6 months. • S. Rapundalo reviews all DBS proposals and serves as the liaison between the CVAB and SAB.
Tour of the Michigan Neonatal Biobank		